

II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DECISION

of 19 May 2000

correcting Directive 98/98/EC adapting to technical progress for the 25th time Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances

(notified under document number C(2000) 1333)

(Text with EEA relevance)

(2000/368/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances⁽¹⁾, as last amended by Directive 1999/33/EC of the European Parliament and of the Council⁽²⁾, and in particular Article 28 thereof,

Whereas:

(1) Annex VI to Directive 67/548/EEC contains a guide to the classification and labelling of dangerous substances and preparations. Annex VI was last amended by Annex 4 to Directive 98/98/EC⁽³⁾. Sections 3.2.3, 3.2.8, 6.2 and 8 of Annex 4 to Directive 98/98/EC are incomplete. In consequence it is necessary to correct Annex 4 to Directive 98/98/EC.

(2) The measures provided for in this Decision are in accordance with the opinion of the Committee on the

adaptation to technical progress of the Directives for the elimination of technical barriers to trade in dangerous substances and preparations,

HAS ADOPTED THIS DECISION:

Article 1

Annex 4 to Directive 98/98/EC is replaced by the Annex to this Decision.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 19 May 2000.

For the Commission
Margot WALLSTRÖM
Member of the
Commission

⁽¹⁾ OJ 196, 16.8.1967, p. 1.

⁽²⁾ OJ L 199, 30.7.1999, p. 57.

⁽³⁾ OJ L 355, 30.12.1998, p. 1.

ANNEX

ANNEX 4

- 1.6. For substances, the data required for classification and labelling may be obtained:
- (a) as regards substances for which the information specified in Annex VII is required, most of the necessary data for classification and labelling appear in the base set. This classification and labelling must be reviewed, if necessary, when further information is available (Annex VIII);
 - (b) as regards other substances (e.g. those referred to in section 1.5), the data required for classification and labelling may, if necessary, be obtained from a number of different sources, for example the results of previous tests, information required by international rules on the transport of dangerous substances, information taken from reference works and the literature or information derived from practical experience. The results of validated structure-activity relationships and expert judgement may also be taken into account where appropriate.

For preparations, the data required for classification and labelling may be obtained:

- (a) if it concerns physicochemical data, by the application of the methods specified in Annex V. For gaseous preparations, a calculation method may be used for flammable and oxidising properties (see Chapter 9);
- (b) if it concerns data on health effects:
 - by the application of the methods specified in Annex V and/or by the application of the conventional method referred to in Article 3(5)(a) to (i) of Directive 88/379/EEC, or, in the case of R 65, by the application of the rules under 3.2.3,
 - however, if it concerns the evaluation of the carcinogenic, mutagenic and reproductive properties, by the application of the conventional method referred to in Article 3(5)(j) to (q) of Directive 88/379/EEC.

Note concerning the performance of animal tests

The performance of animal tests to establish experimental data is subject to the provisions of Directive 86/609/EEC regarding the protection of animals used for experimental purposes.

1.7.2. *Application of the guide criteria for substances*

The guidance criteria set out in this Annex are directly applicable when the data in question have been obtained from test methods comparable with those described in Annex V. In other cases, the available data must be evaluated by comparing the test methods employed with those indicated in Annex V and the rules specified in this Annex for determining the appropriate classification and labelling.

In some cases there may be doubt over the application of the relevant criteria, especially where these require the use of expert judgement. In such cases the manufacturer, distributor or importer should provisionally classify and label the substance on the basis of an assessment of the evidence by a competent person.

Without prejudice to Article 6, where the above procedure has been followed and there is concern over possible inconsistencies then a proposal may be submitted for the entry of the provisional classification into Annex I. The proposal should be made to one of the Member States and should be accompanied by appropriate scientific data (see also section 4.1).

A similar procedure may be followed when information is identified which gives cause for concern over the accuracy of an existing entry in Annex I.

2.2.2.1. *Remarks concerning peroxides*

For the explosive properties, an organic peroxide or preparation thereof in the form in which it is placed on the market is classified according to the criteria in section 2.2.1 on the basis of tests carried out in accordance with the methods given in Annex V.

For the oxidising properties the existing methods in Annex V cannot be applied to organic peroxides.

For substances, organic peroxides not already classified as explosive are classified as dangerous on the basis of their structure (e.g. R-O-O-H; R₁-O-O-R₂).

Preparations not already classified as explosive shall be classified using the calculation method based on the percentage of active oxygen shown in section 9.5.

Any organic peroxide or preparation thereof not already classified as explosive is classified as oxidising, if the peroxide or its formulation contains:

- more than 5% of organic peroxides or,
- more than 0,5% available oxygen from the organic peroxides, and more than 5% hydrogen peroxide.

3.2.3. Harmful

Substances and preparations shall be classified as harmful and assigned the symbol "Xn" and the indication of danger "harmful" in accordance with the criteria specified below. Risk phrases shall be assigned in accordance with the following criteria:

R 22 Harmful if swallowed

Acute toxicity results:

- LD₅₀ per oral, rat: 200 < LD₅₀ ≤ 2 000 mg/kg,
- discriminating dose, oral, rat 50, mg/kg: 100% survival but evident toxicity,
- less than 100% survival at 500 mg/kg, rat oral by the fixed dose procedure. Refer to the evaluation table in the test method Bl(a) of Annex V.

R 21 Harmful in contact with skin

Acute toxicity results:

- LD₅₀ dermal, rat or rabbit: 400 < LD₅₀ ≤ 2 000 mg/kg.

R 20 Harmful by inhalation

Acute toxicity results:

- LC₅₀ inhalation, rat, for aerosols or particulates: 1 < LC₅₀ ≤ 5 mg/litre/4 hr,
- LC₅₀ inhalation, rat, for gases or vapours: 2 < LC₅₀ ≤ 20 mg/litre/4 hr.

R 65 Harmful: may cause lung damage if swallowed

Liquid substances and preparations presenting an aspiration hazard in humans because of their low viscosity

- (a) For substances and preparations containing aliphatic, alicyclic and aromatic hydrocarbons in a total concentration equal to or greater than 10% and having either:
- a flow time of less than 30 seconds in a 3 mm ISO cup according to ISO 2431, or
 - a kinematic viscosity measured by a calibrated glass capillary viscometer in accordance with ISO 3104/3105 of less than 7×10^{-6} m²/sec at 40°C, or
 - a kinematic viscosity derived from measurements of rotational viscometry in accordance with ISO 3129 of less than 7×10^{-6} m²/sec at 40°C.

Note that substances and preparations meeting these criteria need not be classified if they have a mean surface tension greater than 33 mN/m at 25°C as measured by the du Nouy tensiometer or by the test methods shown in Annex V Part A(5);

- (b) For substances and preparations, based on practical experience in humans.

R 40 Possible risk of irreversible effects

- strong evidence that irreversible damage other than the effects referred to in Chapter 4 is likely to be caused by a single exposure by an appropriate route, generally in the abovementioned dose range.

In order to indicate route of administration/exposure one of the following combinations shall be used: R 40/20, R 40/21, R 40/22, R 40/20/21, R 40/20/22, R 40/21/22, R 40/20/21/22.

R 48 Danger of serious damage to health by prolonged exposure

- serious damage (clear functional disturbance or morphological change which has toxicological significance) is likely to be caused by repeated or prolonged exposure by an appropriate route.

Substances and preparations are classified at least as harmful when these effects are observed at levels of the order of:

- oral, rat ≤ 50 mg/kg (body weight)/day,
- dermal, rat or rabbit ≤ 100 mg/kg (body weight)/day,
- inhalation, rat $\leq 0,25$ mg/l, 6 h/day.

These guide values can apply directly when severe lesions have been observed in a subchronic (90 days) toxicity test. When interpreting the results of a subacute (28 days) toxicity test these figures should be increased approximately three fold. If a chronic (two years) toxicity test is available it should be evaluated on a case-by-case basis. If results of studies of more than one duration are available, then those from the study of the longest duration should normally be used.

In order to indicate route of administration/exposure one of the following combinations shall be used: R 48/20, R 48/21, R 48/22, R 48/20/21, R 48/20/22, R 48/21/22, R 48/20/21/22.

3.2.3.1. Comments regarding volatile substances

For certain substances with a high saturated vapour concentration, evidence may be available to indicate effects that give cause for concern. Such substances may not be classified under the criteria for health effects in this guide (3.2.3) or not covered by Section 3.2.8. However, where there is appropriate evidence that such substances may present a risk in normal handling and use, then classification on a case-by-case basis in Annex I may be necessary.

3.2.6.1. Inflammation of the skin

The following risk phrase shall be assigned in accordance with the criteria given:

R 38 Irritating to skin

- substances and preparations which cause significant inflammation of the skin which persists for at least 24 hours after an exposure period of up to four hours determined on the rabbit according to the cutaneous irritation test method cited in Annex V.

Inflammation of the skin is significant if:

- (a) the mean value of the scores for either erythema and eschar formation or oedema formation, calculated over all the animals tested, is two or more;
- (b) or, in the case where the Annex V test has been completed using three animals, either erythema and eschar formation or oedema formation equivalent to a mean value of two or more calculated for each animal separately has been observed in two or more animals.

In both cases all scores at each of the reading times (24, 48 and 72 hours) for an effect should be used in calculating respective mean values.

Inflammation of the skin is also significant if it persists in at least two animals at the end of the observation time. Particular effects, for example, hyperplasia, scaling, discoloration, fissures, scabs and alopecia should be taken into account.

Relevant data may also be available from non-acute animal studies (see comments on R 48, section 2(d)). These are considered significant if the effects seen are comparable to those described above;

- substances and preparations which cause significant inflammation of the skin, based on practical observations in humans on immediate, prolonged or repeated contact;
- organic peroxides, except where evidence to the contrary is available.

Paresthesia: Paresthesia caused in humans by skin contact with pyrethroid pesticides is not regarded as an irritant effect justifying classification as Xi; R 38. The S-phrase S 24 should however be applied for substances seen to cause this effect.

3.2.8. *Other toxicological properties*

Additional risk phrases shall be assigned in accordance with the following criteria (based on experience obtained during compilation of Annex I) to substances and preparations classified by virtue of 2.2.1 to 3.2.7 above and/or Chapters 4 and 5:

R 29 Contact with water liberates toxic gas

For substances and preparations which in contact with water or damp air, evolve very toxic or toxic gases in potentially dangerous amounts, for example, aluminium phosphide, phosphorus pentasulphide.

R 31 Contact with acids liberates toxic gas

For substances and preparations which react with acids to evolve toxic gases in dangerous amounts, for example, sodium hypochlorite, barium polysulphide. For substances used by members of the general public, the use of S 50 (do not mix with ... (to be specified by the manufacturer)) would be more suitable.

R 32 Contact with acids liberates very toxic gas

For substances and preparations which react with acids to evolve very toxic gases in dangerous amounts; e.g. salts of hydrogen cyanide, sodium azide. For substances used by members of the general public, the use of S 50 (do not mix with ... (to be specified by the manufacturer)) would be more suitable.

R 33 Danger of cumulative effects

For substances and preparations when accumulation in the human body is likely and may cause some concern which, however, is not sufficient to justify the use of R 48.

R 64 May cause harm to breastfed babies

For substances and preparations which are absorbed by women and may interfere with lactation or which may be present (including metabolites) in breast milk in amounts sufficient to cause concern for the health of a breastfed child.

For comments on the use and this R-phrase (and in some cases R 33) see section 4.2.3.3.

R 66 Repeated exposure may cause skin dryness or cracking

For substances and preparations which may cause concern as a result of skin dryness, flaking or cracking but which do not meet the criteria for R 38:

based on either:

- practical observation after normal handling and use, or
- relevant evidence concerning their predicted effects on the skin.

See also sections 1.6 and 1.7.

R 67 Vapours may cause drowsiness and dizziness

For volatile substances and preparations containing such substances which cause clear symptoms of central nervous system depression by inhalation and which are not already classified with respect to acute inhalation toxicity (R 20, R 23, R 26, R 40/20, R 39/23 or R 39/26).

The following evidence may be used:

- (a) data from animal studies showing clear signs of CNS depression such as narcotic effects, lethargy, lack of coordination (including loss of righting reflex) and ataxia either:
 - at concentrations/exposure times not exceeding 20 mg/l/4 h or,
 - for which the ratio of the effect concentration at ≤ 4 h to the saturated vapour concentration (SVC) at 20 °C is $\leq 1/10$;
- b) practical experience in humans (e.g. narcosis, drowsiness, reduced alertness, loss of reflexes, lack of coordination, vertigo) from well documented reports under comparable exposure conditions to the effects specified above for animals.

See also sections 1.6 and 1.7.

For other supplementary risk phrases see section 2.2.6.

4.1.2. If a manufacturer, distributor or importer has information available which indicates that a substance should be classified and labelled in accordance with the criteria given in section 4.2.1, 4.2.2 or 4.2.3, he shall provisionally label the substance in accordance with these criteria, on the basis of the assessment of the evidence by a competent person.

4.1.3. The manufacturer, distributor or importer shall submit as soon as possible a document summarising all relevant information to one Member State in which the substance is placed on the market. This summary document should include a bibliography containing all relevant references, including any relevant unpublished data.

4.1.4. Furthermore, a manufacturer, distributor or importer who has new data which are relevant to the classification and labelling of a substance in accordance with the criteria given in section 4.2.1, 4.2.2 or 4.2.3, shall submit this data as soon as possible to one Member State in which the substance is placed on the market.

5.2.2. *Non-aquatic environment*

5.2.2.1. Substances shall be classified as dangerous for the environment and assigned the symbol "N" and the appropriate indication of danger, and assigned risk phrases in accordance with the following criteria:

R 54: Toxic to flora

R 55: Toxic to fauna

R 56: Toxic to soil organisms

R 57: Toxic to bees

R 58: May cause long term adverse effects on the environment

Substances which on the basis of the available evidence concerning their properties, persistence, potential to accumulate and predicted or observed environmental fate and behaviour may present a danger, immediate or long-term and/or delayed, to the structure and/or functioning of natural ecosystems other than those covered under 5.2.1. Detailed criteria will be elaborated later.

5.2.2.2. Substances shall be classified as dangerous for the environment and assigned the symbol "N" and the appropriate indication of danger, and assigned risk phrases in accordance with the following criteria:

R 59: Dangerous for the ozone layer

Substances which on the basis of the available evidence concerning their properties and their predicted or observed environmental fate and behaviour may present a danger to the structure and/or functioning of the stratospheric ozone layer. This includes the substances which are listed in Annex I to Council Regulation (EC) No 3093/94 on substances that deplete the ozone layer (OJ L 333, 22.12.1994, p. 1) and its subsequent amendments.

6.2. Safety phrases for substances and preparations.

S 1 Keep locked up

- Applicability:
 - very toxic, toxic and corrosive substances and preparations,
- Criteria for use:
 - obligatory for those substances and preparations mentioned above if sold to the general public.

S 2 Keep out of the reach of children

- Applicability:
 - all dangerous substances and preparations,
- Criteria for use:
 - obligatory for all dangerous substances and preparations sold to the general public, except for those only classified as dangerous for the environment.

S 3 Keep in a cool place

- Applicability:
 - organic peroxides,
 - other dangerous substances and preparations having a boiling point $\leq 40^{\circ}\text{C}$,
- Criteria for use:
 - obligatory for organic peroxides unless S 47 is used,
 - recommended for other dangerous substances and preparations having a boiling point $\leq 40^{\circ}\text{C}$.

S 4 Keep away from living quarters

- Applicability:
 - very toxic and toxic substances and preparations,
- Criteria for use:
 - normally limited to very toxic and toxic substances and preparations when desirable to supplement S 13; for example when there is an inhalation risk and the substance or preparation should be stored away from living quarters. The advice is not intended to preclude proper use of the substance or preparation in living quarters.

S 5 Keep contents under ... (appropriate liquid to be specified by the manufacturer)

- Applicability:
 - spontaneously flammable solid substances and preparations,
- Criteria for use:
 - normally limited to special cases, for example, sodium, potassium or white phosphorous.

S 6 Keep under ... (inert gas to be specified by the manufacturer)

- Applicability:
 - dangerous substances and preparations which must be kept under an inert atmosphere,
- Criteria for use:
 - normally limited to special cases, for example, certain organometallic compounds.

S 7 Keep container tightly closed

- Applicability:
 - organic peroxides,
 - substances and preparations which can give off very toxic, toxic, harmful or extremely flammable gases,
 - substances and preparations which in contact with moisture give off extremely flammable gases,
 - highly flammable solids,
- Criteria for use:
 - obligatory for organic peroxides,
 - recommended for the other fields of application mentioned above.

S 8 Keep container dry

- Applicability:
 - substances and preparations which may react violently with water,
 - substances and preparations which on contact with water liberate extremely flammable gases,
 - substances and preparations which on contact with water liberate very toxic or toxic gases,
- Criteria for use:
 - normally limited to the fields of application mentioned above when necessary to reinforce warnings given by R 14, R 15 in particular, and R 29.

S 9 Keep container in a well-ventilated place

- Applicability:
 - volatile substances and preparations which may give off very toxic, toxic or harmful vapours,
 - extremely flammable or highly flammable liquids and extremely flammable gases,
- Criteria for use:
 - recommended for volatile substances and preparations which may give off very toxic, toxic or harmful vapours,
 - recommended for extremely flammable or highly flammable liquids or extremely flammable gases.

S 12 Do not keep the container sealed

- Applicability:
 - substances and preparations which will by giving off gases or vapours be liable to burst the container,
- Criteria for use:
 - normally limited to the special cases mentioned above.

S 13 Keep away from food, drink and animal feedingstuffs

- Applicability:
 - very toxic, toxic and harmful substances and preparations,
- Criteria for use:
 - recommended when such substances and preparations are likely to be used by the general public.

S 14 Keep away from ... (incompatible materials to be indicated by the manufacturer)

- Applicability:
 - organic peroxides,
- Criteria for use:
 - obligatory for and normally limited to organic peroxides. However, may be useful in exceptional cases when incompatibility is likely to produce a particular risk.

S 15 Keep away from heat

- Applicability:
 - substances and preparations which may decompose or which may react spontaneously under the effect of heat,
- Criteria for use:
 - normally limited to special cases, for example monomers, but not assigned if risk phrases R 2, R 3 and/or R 5 have already been applied.

S 16 Keep away from sources of ignition — no smoking

- Applicability:
 - extremely flammable or highly flammable liquids and extremely flammable gases,
- Criteria for use:
 - recommended for the substances and preparations mentioned above but not assigned if risk phrases R 2, R 3 and/or R 5 have already been applied.

S 17 Keep away from combustible material

- Applicability:
 - substances and preparations which may form explosive or spontaneously flammable mixtures with combustible material,
- Criteria for use:
 - available for use in special cases, for example to emphasise R 8 and R 9.

S 18 Handle and open container with care

- Applicability:
 - substances and preparations liable to produce an overpressure in the container,
 - substances and preparations which may form explosive peroxides,
- Criteria for use:
 - normally limited to the abovementioned cases when there is risk of damage to the eyes and/or when the substances and preparations are likely to be used by the general public.

S 20 When using do not eat or drink

- Applicability:
 - very toxic, toxic and corrosive substances and preparations,
- Criteria for use:
 - normally limited to special cases (for example arsenic and arsenic compounds; (fluoracetates) in particular when any of these are likely to be used by the general public.

S 21 When using do not smoke

- Applicability:
 - substances and preparations which produce toxic products on combustion.
- Criteria for use:
 - normally limited to special cases (e.g. halogenated compounds).

S 22 Do not breathe dust

- Applicability:
 - all solid substances and preparations dangerous for health,
- Criteria for use:
 - obligatory for those substances and preparations mentioned above to which R 42 is assigned,
 - recommended for those substances and preparations mentioned above which are supplied in the form of an inhalable dust and for which the health hazards following inhalation are not known.

S 23 Do not breathe gas/fumes/vapour/spray (appropriate wording to be specified by the manufacturer)

- Applicability:
 - all liquid or gaseous substances and preparations dangerous to health,
- Criteria for use:
 - obligatory for those substances and preparations mentioned above to which R 42 is assigned,
 - obligatory for substances and preparations intended for use by spraying. Either S 38 or S 51 must be ascribed in addition,
 - recommended when it is necessary to draw the attention of the user to inhalation risks not mentioned in the risk phrases which have to be ascribed.

S 24 Avoid contact with skin

- Applicability:
 - all substances and preparations dangerous for health,
- Criteria for use:
 - obligatory for those substances and preparations to which R 43 has been ascribed, unless S 36 has also been ascribed,
 - recommended when it is necessary to draw the attention of the user to skin contact risks not mentioned in the risk phrases (e.g. paresthesia) which have to be ascribed. However, may be used to emphasise such risk phrases.

S 25 Avoid contact with eyes

- Applicability:
 - all substances and preparations dangerous to health,
- Criteria for use:
 - recommended when it is necessary to draw the attention of the user to eye contact risks not mentioned in the risk phrases which have to be applied. However, may be used to emphasise such risk phrases,
 - recommended for substances ascribed R 34, R 35, R 36 or R 41 which are likely to be used by the general public.

S 26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice

- Applicability:
 - corrosive or irritant substances and preparations,
- Criteria for use:
 - obligatory for corrosive substances and preparations and those to which R 41 has already been ascribed,
 - recommended for irritant substances and preparations to which the risk phrase R 36 has already been ascribed.

S 27 Take off all contaminated clothing immediately

- Applicability:
 - very toxic, toxic or corrosive substances and preparations,
- Criteria for use:
 - obligatory for very toxic substances and preparations to which R 27 has been ascribed and which are likely to be used by the general public.
 - recommended for very toxic substances and preparations to which R 27 has been ascribed used in industry. However, this safety phrase should not be used if S 36 has been ascribed.
 - recommended for toxic substances and preparations to which R 24 has been ascribed as well as corrosive substances and preparations which are likely to be used by the general public.

S 28 After contact with skin, wash immediately with plenty of ... (to be specified by the manufacturer).

- Applicability:
 - very toxic, toxic or corrosive substances and preparations,
- Criteria for use:
 - obligatory for very toxic substances and preparations,
 - recommended for the other substances and preparations mentioned above, in particular when water is not the most appropriate rinsing fluid,
 - recommended for corrosive substances and preparations which are likely to be used by the general public.

S 29 Do not empty into drains

- Applicability:
 - extremely or highly flammable liquids immiscible with water,
 - very toxic and toxic substances and preparations,
 - substances dangerous for the environment,
- Criteria for use:
 - obligatory for substances dangerous for the environment and assigned the symbol "N", which are likely to be used by the general public, unless this is the intended use.
 - recommended for other substances and preparations mentioned above which are likely to be used by the general public, unless this is the intended use.

S 30 Never add water to this product

- Applicability:
 - substances and preparations which react violently with water,
- Criteria for use:
 - normally limited to special cases (e.g. sulphuric acid) and may be used, as appropriate, to give the clearest possible information, either to emphasise R 14 or as an alternative to R 14.

S 33 Take precautionary measures against static discharges

- Applicability:
 - extremely or highly flammable substances and preparations,
- Criteria for use:
 - recommended for substances and preparations used in industry which do not absorb moisture. Virtually never used for substances and preparations as placed on the market for use by the general public.

S 35 This material and its container must be disposed of in a safe way.

- Applicability:
 - all dangerous substances and preparations,
- Criteria for use:
 - recommended for substances and preparations where special guidance is needed to ensure proper disposal.

S 36 Wear suitable protective clothing

- Applicability:
 - organic peroxides,
 - very toxic, toxic or harmful substances and preparations,
 - corrosive substances and preparations,
- Criteria for use:
 - obligatory for very toxic and corrosive substances and preparations,
 - obligatory for those substances and preparations to which either R 21 or R 24 has been ascribed,
 - obligatory for category 3 carcinogens, mutagens and substances toxic to reproduction unless the effects are produced solely by inhalation of the substance or preparation,
 - obligatory for organic peroxides,
 - recommended for toxic substances and preparations if the LD₅₀ dermal value is unknown but the substance or preparation is likely to be toxic through skin contact,
 - recommended for substances and preparations used in industry which are liable to damage health by prolonged exposure.

S 37 Wear suitable gloves

- Applicability:
 - very toxic, toxic, harmful or corrosive substances and preparations,
 - organic peroxides,
 - substances and preparations irritating to the skin or causing sensitisation by skin contact,

- Criteria for use:
 - obligatory for very toxic and corrosive substances and preparations,
 - obligatory for those substances and preparations to which either R 21, R 24 or R 43 has been ascribed,
 - obligatory for category 3 carcinogens, mutagens and substances toxic to reproduction unless the effects are produced solely by inhalation of the substances and preparations,
 - obligatory for organic peroxides,
 - recommended for toxic substances and preparations if the LD₅₀ dermal value is unknown but the substance or preparation is likely to be harmful by skin contact,
 - recommended for substances and preparations irritating to the skin.

S 38 In case of insufficient ventilation, wear suitable respiratory equipment

- Applicability:
 - very toxic or toxic substances and preparations,
- Criteria for use:
 - normally limited to special cases involving the use of very toxic or toxic substances and preparations in industry or in agriculture.

S 39 Wear eye/face protection

- Applicability:
 - organic peroxides,
 - corrosive substances and preparations, including irritants which give rise to risk of serious damage to the eyes.
 - very toxic and toxic substances and preparations,
- Criteria for use:
 - obligatory for those substances and preparations to which R 34, R 35 or R 41 have been ascribed,
 - obligatory for organic peroxides,
 - recommended when it is necessary to draw the attention of the user to eye contact risks not mentioned in the risk phrases which have to be ascribed,
 - normally limited to exceptional cases for very toxic and toxic substances and preparations, where there is a risk of splashing and they are likely to be easily absorbed by the skin.

S 40 To clean the floor and all objects contaminated by this material use ... (to be specified by the manufacturer)

- Applicability:
 - all dangerous substances and preparations,
- Criteria for use:
 - normally limited to those dangerous substances and preparations for which water is not considered to be a suitable cleansing agent (e.g. where absorption by powdered material, dissolution by solvent, etc. is necessary) and where it is important for health and/or safety reasons to provide a warning on the label.

S 41 In case of fire and/or explosion do not breathe fumes

- Applicability:
 - dangerous substances and preparations which on combustion give off very toxic or toxic gases,
- Criteria for use:
 - normally limited to special cases.

S 42 During fumigation/spraying wear suitable respiratory equipment (appropriate wording to be specified by the manufacturer)

- Applicability:
 - substances and preparations intended for such use but which may endanger the health and safety of the user unless proper precautions are taken,
- Criteria for use:
 - normally limited to special cases.

S 43 In case of fire use ... (indicate in the space the precise type of fire-fighting equipment. If water increases the risk add: Never use water)

- Applicability:
 - extremely flammable, highly flammable and flammable substances and preparations,
- Criteria for use:
 - obligatory for substances and preparations which, in contact with water or damp air, evolve extremely flammable gases,
 - recommended for extremely flammable, highly flammable and flammable substances and preparations, particularly when they are immiscible with water.

S 45 In case of accident or if you feel unwell seek medical advice immediately (show the label where possible).

- Applicability:
 - very toxic substances and preparations,
 - toxic and corrosive substances and preparations,
 - substances and preparations causing sensitisation by inhalation,
- Criteria for use:
 - obligatory for the substances and preparations mentioned above.

S 46 If swallowed, seek medical advice immediately and show this container or label

- Applicability:
 - all dangerous substances and preparations other than those which are very toxic, toxic, corrosive or dangerous to the environment,
- Criteria for use:
 - obligatory for all dangerous substances and preparations mentioned above which are likely to be used by the general public, unless there is no reason for fear any danger from swallowing, particularly by children.

S 47 Keep at temperature not exceeding ... °C (to be specified by the manufacturer)

- Applicability:
 - substances and preparations which become unstable at a certain temperature,
- Criteria for use:
 - normally limited to special cases (e.g. certain organic peroxides).

S 48 Keep wetted with ... (appropriate material to be specified by the manufacturer)

- Applicability:
 - substances and preparations which may become very sensitive to sparks, friction or impact if allowed to dry out,
- Criteria for use:
 - normally limited to special cases, for example nitrocelluloses.

S 49 Keep only in the original container

- Applicability:
 - substances and preparations sensitive to catalytic decomposition,
- Criteria for use:
 - substances and preparations sensitive to catalytic decomposition, for example certain organic peroxides.

S 50 Do not mix with ... (to be specified by the manufacturer)

- Applicability:
 - substances and preparations which may react with the specified product to evolve very toxic or toxic gases,
 - organic peroxides,
- Criteria for use
 - recommended for substances and preparations mentioned above which are likely to be used by the general public, when it is a better alternative to R 31 or R 32,
 - obligatory with certain peroxides which may give violent reaction with accelerators or promoters.

S 51 Use only in well-ventilated areas

- Applicability:
 - substances and preparations likely to or intended to produce vapours, dusts, sprays, fumes, mists, etc. which give rise to inhalation risks or to a fire or explosion risk,
- Criteria for use:
 - recommended when use of S 38 would not be appropriate. Thus important when such substances and preparations are likely to be used by the general public.

S 52 Not recommended for interior use on large surface areas

- Applicability:
 - volatile, very toxic, toxic and harmful substances and preparations containing them,
- Criteria for use:
 - recommended when damage to health is likely to be caused by prolonged exposure to these substances by reason of their volatilisation from large treated surfaces in the home or other enclosed places where persons congregate.

S 53 Avoid exposure — Obtain special instructions before use

- Applicability:
 - substances and preparations that are carcinogenic, mutagenic and/or toxic to reproduction,
- Criteria for use:
 - obligatory for the abovementioned substances and preparations to which at least one of the following R-phrases has been assigned: R 45, R 46, R 49, R 60 or R 61.

S 56 Dispose of this material and its container to hazardous or special waste collection point

- Applicability:
 - all dangerous substances and preparations,
- Criteria for use:
 - recommended for all dangerous substances and preparations likely to be used by the general public for which special disposal is required.

S 57 Use appropriate containment to avoid environmental contamination

- Applicability:
 - substances which have been assigned the symbol "N",
- Criteria for use:
 - normally limited to substances not likely to be used by the general public.

S 59 Refer to manufacturer/supplier for information on recovery/recycling

- Applicability:
 - all dangerous substances and preparations,
- Criteria for use:
 - obligatory for substances dangerous for the ozone layer,
 - recommended for other substances and preparations for which recovery/recycling is recommended.

S 60 This material and its container must be disposed of as hazardous waste

- Applicability:
 - all dangerous substances and preparations,
- Criteria for use:
 - recommended for substances and preparations not likely to be used by the general public and where S 35 is not assigned.

S 61 Avoid release to the environment. Refer to special instructions/safety data sheet

- Applicability:
 - substances dangerous for the environment,
- Criteria for use:
 - normally used for substances which have been assigned the symbol "N",
 - recommended for all substances classified dangerous for the environment not covered above.

S 62 If swallowed, do not induce vomiting: seek medical advice immediately and show this container or label.

- Applicability:
 - substances and preparations classified as harmful with R 65 in accordance with the criteria in section 3.2.3,
 - not applicable to substances and preparations which are placed on the market in aerosol containers (or in containers fitted with a sealed spray attachment), see sections 8 and 9,
- Criteria for use:
 - obligatory for substances and preparations mentioned above, if sold to, or likely to be used by the general public, except when S 45 or S 46 are obligatory,
 - recommended for the substances and preparations mentioned above when used in industry, except where S 45 or S 46 are obligatory,

S 63 In case of accident by inhalation: remove casualty to fresh air and keep at rest

- Applicability:
 - very toxic and toxic substances and preparations (gases, vapours, particulates, volatile liquids),
 - substances and preparations causing respiratory sensitisation,

- Criteria for use:
 - obligatory for substances and preparation to which R 26, R 23 or R 42 has been assigned which are likely to be used by the general public in a way which could result in inhalation

S 64 If swallowed, rinse mouth with water, (only if the person is conscious).

- Applicability:
 - corrosive or irritant substances and preparations,
- Criteria for use:
 - recommended for the above substances and preparations which are likely to be used by the general public and where the above treatment is suitable.

7.5.2. *Choice of safety phrases*

The final choice of safety phrases must have regard to the risk phrases indicated on the label and to the intended use of the substance or preparation:

- as a general rule, a maximum of four S-phrases shall suffice to formulate the most appropriate safety advice; for this purpose the combined phrases listed in Annex IV shall be regarded as single phrases,
- in the case of S-phrases concerning disposal, one S-phrase shall be used, unless it is clear that disposal of the material and its container does not present a danger for human health or the environment. In particular, advice on safe disposal is important for substances and preparations sold to the general public,
- some R-phrases become superfluous if a careful selection is made of S-phrases and vice versa; S-phrases which obviously correspond to R-phrases will appear on the label only if it is intended to emphasise a specific warning,
- particular attention must be given, in the choice of safety phrases, to the foreseen conditions of use of certain substances and preparations, for example spraying or other aerosol effects. Phrases should be chosen with the intended use in view,
- the safety phrases S 1, S 2 and S 45 are obligatory for all very toxic, toxic and corrosive substances and preparations sold to the general public,
- the safety phrases S 2 and S 46 are obligatory for all other dangerous substances and preparations (except those only classified as dangerous to the environment) sold to the general public.

Where the phrases selected according to the strict criteria in 6.2 result in redundancy or ambiguity or are clearly unnecessary given the specific product/package then some phrases may be deleted.

8. SPECIAL CASES: SUBSTANCES

8.1. **Mobile gas cylinders**

For mobile gas cylinders the requirements concerning labelling are considered to be satisfied when they are in agreement with Article 23 or Article 24(6)b.

However, by way of derogation from Article 24(1) and 82), one of the following alternatives can be used for gas cylinders with a water capacity of less than or equal to 150 litres:

- the format and dimensions of the label can follow the prescriptions of the ISO standard ISO/DP 7225,
- the information specified in Article 23(2) may be provided on a durable information disc or label held captive on the cylinder.

8.2. Gas containers intended for propane, butane or liquefied petroleum gas (LPG)

These substances are classified in Annex I. Although classified in accordance with Article 2, they do not present a danger to human health when they are placed on the market in closed refillable cylinders or in non-refillable cartridges within the scope of EN 417 as fuel gases which are only released for combustion.

These cylinders or cartridges must be labelled with the appropriate symbol and the R- and S-phrases concerning flammability. No information concerning the effects on human health is required on the label. However, the information concerning effects on human health which should have appeared on the label shall be transmitted to the professional user by the person responsible for placing the substance on the market in the format foreseen in Article 27 of the Directive. For the consumer, sufficient information shall be transmitted to enable them to take all necessary measures for health and safety as foreseen in Article 1(3) of Directive 91/155/EEC, as modified by Directive 93/112/EEC.

8.3. Metals in massive form

These substances are classified in Annex I or shall be classified in accordance with Article 6. However, some of these substances, although classified in accordance with Article 2 do not present a danger to human health by inhalation, ingestion or contact with skin or to the aquatic environment in the form in which they are placed on the market. Such substances do not require a label according to Article 23. However, all the information which should have appeared on the label shall be transmitted to the user by the person responsible for placing the metal on the market, in a format foreseen in Article 27.

8.4. Substances classified with R 65

Substances classified as harmful on the basis of an aspiration hazard need not be labelled as harmful with R 65 when placed on the market in aerosol containers or in containers fitted with a sealed spray attachment.'
